

Purpose of Meeting:

Review Section 3 Deficiencies and Discuss Resubmission of Chlormequat Chloride petition by Eastman/Taminco

Meeting Date:

June 4, 2019 from 2:30 – 3:00 pm

Attendees:

Heather Garvie – EPA – garvie.heather@epa.gov

Lindsay Roe – EPA – [[HYPERLINK "mailto:roe.lindsay@epa.gov"](mailto:roe.lindsay@epa.gov)]

Cynthia Giles-Parker – EPA – [[HYPERLINK "mailto:giles-parker.cynthia@epa.gov"](mailto:giles-parker.cynthia@epa.gov)]

Jean Holmes – EPA – holmes.jean@epa.gov

Katrina White – EPA – [[HYPERLINK "mailto:white.katrina@epa.gov"](mailto:white.katrina@epa.gov)]

Karen Milians – EPA – [[HYPERLINK "mailto:milians.karen@epa.gov"](mailto:milians.karen@epa.gov)]

Cameron Douglass – EPA – [[HYPERLINK "mailto:douglass.cameron@epa.gov"](mailto:douglass.cameron@epa.gov)]

Jessica McLaughlin – Eastman/Taminco – [[HYPERLINK "mailto:jessicamclaughlin@eastman.com"](mailto:jessicamclaughlin@eastman.com)]

John Hott – Eastman/Taminco – [[HYPERLINK "mailto:johnhott@eastman.com"](mailto:johnhott@eastman.com)]

Rebecca Currie – Eastman/Taminco – [[HYPERLINK "mailto:rebeccacurrie@eastman.com"](mailto:rebeccacurrie@eastman.com)]

Juli Mann – Steptoe & Johnson (Consultant to Eastman/Taminco) - [[HYPERLINK "mailto:JMann@steptoe.com"](mailto:JMann@steptoe.com)]

Notes:

Text in Black is information that was discussed during the meeting

Text in Red is information that was sent by Heather Garvie as a post-meeting follow up

Meeting notes:

- Taminco outlined the history of chlormequat chloride, regarding their interest in the chemical.
 - December 7, 2018 – Submission of Section 3 Registration to EPA
 - March 26, 2019 – Received 10 Day Deficiency Letter from EPA
 - March 27, 2019 – Eastman submitted response to 10 Day Deficiency Letter
 - May 8, 2019 – Received rejection letter from EPA
- Taminco outlined the deficiencies that need to be fulfilled to successfully pass a future technical screen for their Section 3 registration of chlormequat chloride for first food use.
 - 835.2410 – Soil Photolysis
 - 850.4500 – Non-Vascular Aquatic Plant Toxicity - marine diatom (*Skeletonema costatum*)
 - 850.4500 – Non-Vascular Aquatic Plant Toxicity - freshwater diatom (*Skeletonema costatum*)
 - 850.1350 – Chronic Saltwater Vertebrate
 - 850.1400 – Chronic Saltwater Invertebrate
 - 850.6100 – The associated Independent Laboratory Validation for the Environmental Chemistry Method in water
- Taminco will conduct all the noted deficiencies listed above in addition to:

- 850.4500 – Non-Vascular Aquatic Plant Toxicity - freshwater green alga (*Raphidocelis subcapitata*)
- Taminco expects to resubmit a Section 3 registration petition for a TGA of chlormequat chloride and an end-use product containing 54.78% chlormequat chloride in early 2020.
- Taminco confirmed they will submit a waiver request for the Anaerobic Soil Metabolism to support their Section 3 submission.
 - EPA agreed the submission of an Aerobic Soil Metabolism study, an Anaerobic Aquatic Metabolism study, and a scientific Anaerobic Soil Metabolism study waiver would be a strong package to support their product registration.
- EPA suggested submitting the scientific Anaerobic Soil Metabolism study waiver as a PRIA R124 action for absolute confirmation of the waiver's acceptability.
 - This has a 6-month timing and \$2,530 fee.
- EPA confirmed, if Taminco's label uses and data packet remain the same for their future Section 3 petition and Taminco addresses all the deficiencies outlined in the May 8, 2019 rejection letter, no additional data will be required to pass the future technical screen.
- Taminco is in an agreement with Fine Agrochemical for the registration review of chlormequat chloride.
 - Fine Agrochemical is citing Taminco studies to support the current DCI for chlormequat chloride that was published on February 12, 2019.

Post-meeting follow up:

- EPA followed up via email regarding the registration review of chlormequat chloride. The docket ID# is EPA-HQ-OPP-2015-0816. Per the DCI, some of the studies are due in 12 months and some are due in 24 months. Barring any time extensions, Taminco will be required to have data to support all studies that are due in 12 months, before they submit their Section 3 petition in early 2020. Taminco will be required to state in their application how they intend to support the studies that are due in 24 months (February 12, 2021), as these studies will be due before their PRIA due date for their new application. Data to support the 24-month studies must be submitted to EPA before their new Section 3 petition is approved.
 - Taminco currently has data to support all studies listed in the chlormequat chloride registration review, except the Algal Toxicity studies and the Tier II and Tier III honeybee studies. Per the deficiencies outlined by EPA, Taminco is conducting the Algal Toxicity studies. Taminco is waiting for feedback from EPA on the Tier I honeybee studies before any additional Tier II or Tier III honeybee studies are initiated.